

REMARKS

The amendments to the specification and claims find support in the specification and claims as filed. For example, at page 4, lines 1-4, the inventors state: "the invention provides an arabinogalactan protein composition having a weight average molecular weight of at least 100 kiloDaltons isolated from the purified arabinogalactan composition of the first aspect of this invention." At page 9, lines 27-30, referring to the novel arabinogalactan protein compositions, the specification states: "It contains about 95% carbohydrates (including the carbohydrates that glycosylate the protein core of the arabinogalactan protein) and about 5% proteins. Hydroxyproline, accounting for about 20% of its total amino acid content, is a characteristic of the arabinogalactan protein." Further details of the claimed invention may be found, for example, at pages 9-10; pages 27-28; and elsewhere in the specification. No new matter is added by way of the amendments.

Claims 21-38 are pending in the application, with claims 29-38 withdrawn from consideration pursuant to a final Restriction Requirement made final in the Office Action mailed on June 26, 2003. With the present amendment, claims 29-38 are canceled without prejudice to the presentation of their subject matter in continuation or divisional applications.

Claims 21-28 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Dan Bensky et al., Hson-Mou Chang et al., Chu et al., CN 1047806 or EP 441278. Claims 21-28 also stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Dan Bensky et al., Hson-Mou Chang et al., Chu et al., CN 1047806 or EP 441278.

General Remarks

Applicants note that the present invention, as defined in the amended claims, is directed to an arabinogalactan protein composition that has been found to produce desirable effects in mammals. As disclosed in the specification, the novel arabinogalactan protein compositions of the invention include about 5% protein (page 9, line 28). The arabinogalactan protein includes hydroxyproline as about 20% of its total amino acid content (page 9, line 29). Please note that the proteins in these

arabinogalactan protein compositions are a desired component, and not a contaminant or inert impurity. Thus, unlike the cited prior art, not only are the claimed compositions directed to arabinogalactan compositions that include proteins, but these protein compositions in addition have an average molecular weight of at least 100 kiloDaltons, and comprise about 5% protein, the protein having an amino acid content of about 20% hydroxyproline.

The Rejections of Claims 21-28 under 35 U.S.C. § 102(b)

Claims 21-28 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Dan Bensky et al., Hson-Mou Chang et al., Chu et al., CN 1047806 or EP 441278. Applicants traverse the rejections of claims 21-28 as allegedly anticipated by the cited references. The Examiner suggests that, since the references discuss standard purification techniques, the extracts of the references will "have the same molecular weight as in applicant's invention." Applicants respectfully submit that one of skill in the art would recognize that different purification procedures (e.g., different filtration procedures) would lead to extracts with different molecular weights. Moreover, as is discussed in more detail below, applicants submit that the cited references fail to anticipate claims 21-28.

Anticipation under 35 U.S.C. § 102 requires that "every element of the claimed invention be identically shown in a single reference." (*In re Bond*, 910 F.2d 831,832 (Fed. Cir. 1990). However, applicants note that none of the cited references discuss arabinogalactan protein compositions; moreover, the cited references do not discuss the percentage of protein of such arabinogalactan protein compositions, nor do the cited references discuss the presence of hydroxyproline, nor the percentage of the amino acid composition of such arabinogalactan protein compositions that is hydroxyproline.

Dan Bensky et al. discusses Radix Astragali (the root of *Astragalus membranaceus*), and specifies a number of its uses in traditional Chinese medicine. It refers to "decoctions of the root of *Astragalus membranaceus*" and injections of these decoctions into laboratory animals. However, Dan Bensky et al. fails to discuss purified arabinogalactan protein compositions, fails to discuss arabinogalactan protein

compositions having a weight average molecular weight of at least 100 kiloDaltons, and fails to discuss the amino acid composition of arabinogalactan protein.

Hson-Mou Chang et al. discusses "Huangqi" (the root of *Astragalus membranaceus*), and specifies a number of its uses in traditional Chinese medicine. It refers to its decoctions, and their effects when injected into laboratory animals and in some human clinical studies. However, Hson-Mou Chang et al. does not discuss arabinogalactan protein compositions, nor arabinogalactan protein compositions having a weight average molecular weight of at least 100 kiloDaltons, nor having 5% protein, nor that the amino acid composition of the protein includes 20% hydroxyproline.

Chu et al. discloses a partially purified fraction (F3) derived from *Astragalus membranaceus* and having an estimated molecular weight of 20,000-25,000. However, Chu et al. fail to discuss an arabinogalactan protein composition having a weight average molecular weight of at least 100 kiloDaltons (in fact Chu et al. specifically disclose a fraction having a molecular weight of 20-25 kiloDaltons). Moreover, Chu et al. does not provide any teaching about the presence, or the amount, of protein, nor of the fraction of protein in an arabinogalactan protein composition that is hydroxyproline.

CN1047806 was provided only as a one-page entry from Derwent, of which the only relevant information was "Injection compsn. for anal-fistula - comprises Gleditia sinensis, Astragalus membranaceus, Coptis chinensis, and centipede." There is no disclosure of a purified arabinogalactan protein composition, nor of an arabinogalactan protein composition having a weight average molecular weight of at least 100 kiloDaltons, nor having 5% protein, nor of such protein comprising 20% hydroxyproline as required by the present claims.

EP 0 441 278 discusses "Astraglucones" and their mixture with other polysaccharides extracted from the roots and rhizomes of *Astragalus membranaceus*. EP 0 441 278 A1 states "The present invention refers to polysaccharides with molecular weights between 120000 and 500,000 daltons" (column 1, lines 1-3) and nowhere discusses arabinogalactan protein compositions. This reference thus refers to glucose-based polysaccharides and not to the arabinogalactan protein compositions as claimed in the present application. As described in column 2 of **EP 0 441 278**, the method of

preparation of the "Astraglucones" would denature proteins; and is thus incapable of preparation of the arabinogalactan protein compositions of the present invention. Unlike the glucose-based polysaccharide "Astraglucones," the arabinogalactan protein compositions include proteins that are highly glycosylated proteins, predominantly with arabinose and galactose. Thus, since EP 0441278 A1 does not discuss proteins, but is instead being directed to arabinogalactan polysaccharides, and in particular does not discuss arabinogalactan protein compositions having a weight average molecular weight of at least 100 kiloDaltons, EP 0441278 A1 does not disclose the claimed invention and so does not anticipate it.

Thus, as discussed above, the cited references fail to disclose arabinogalactan protein compositions, arabinogalactan protein compositions comprising about 5% protein, and arabinogalactan proteins having an amino acid content of about 20% hydroxyproline. Failing to discuss at least these elements of claims 21-28, Dan Bensky et al., Hson-Mou Chang et al., Chu et al., CN1047806 and EP 0 441 278 do not anticipate the subject matter of claims 21-28.

Accordingly, applicants submit that claims 21-28 are not anticipated by the cited references, and that the rejections of claims 21-28 under 35 U.S.C. § 102(b) are overcome.

The Rejections of Claims 21-28 under 35 U.S.C. § 103(a)

Claims 21-28 also stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Dan Bensky et al., Hson-Mou Chang et al., Chu et al., CN 1047806 or EP 441278. The Examiner suggests that "the claims are obvious since the extract is purified by known techniques." However, the claimed arabinogalactan protein compositions are not described or suggested by any cited reference or by any combination of the cited references. Applicants traverse the rejections of claims 21-28 as allegedly obvious over the cited references.

In order to establish a prima facie case of obviousness, there must be 1) some suggestion or motivation in the art or in the knowledge generally available to one of ordinary skill in the art, to modify or to combine the reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As discussed above, the cited references all lack many elements of the claimed invention. Thus, for example, the cited references fail to disclose arabinogalactan protein compositions, fail to disclose arabinogalactan protein compositions comprising about 5% protein, and fail to disclose arabinogalactan proteins having an amino acid content of about 20% hydroxyproline. Moreover, there is no suggestion in the cited references that the references could be combined to provide the missing elements, nor do the cited references provide any motivation to supply the missing elements by combination of references or by any other means. None of the cited references discuss arabinogalactan protein compositions, nor the fraction of an arabinogalactan protein composition that is protein, nor the presence or amount of hydroxyproline in such an arabinogalactan protein. Lacking disclosure of the arabinogalactan protein compositions, there is no suggestion or motivation in the cited references to provide such compositions, nor is there any suggestion or motivation provided that would lead

one of ordinary skill in the art to have a reasonable expectation of success were such a combination attempted.

Accordingly, the cited references failing to provide all the elements of the claimed invention; failing to provide a suggestion, or any motivation to combine references to provide the claimed invention, and failing to provide a reasonable expectation of success, applicants respectfully submit that the rejections of claims 21-28 under 35 U.S.C. 103(a) are overcome.

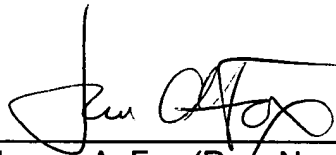
CONCLUSION

Applicants respectfully submit that the rejections of claims 21-38 are overcome, that all claims are in condition for allowance, and request reconsideration and allowance of all pending claims. The Examiner is invited to contact the undersigned attorney at the telephone number indicated below should he find that there are any further issues outstanding.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. **08-1641** citing Attorney Docket No. **22001-0003**.

Respectfully submitted,

Date: December 17, 2003

By: 
James A. Fox (Reg. No. 38,455)

HELLER, EHRMAN WHITE & McAULIFFE LLP
275 Middlefield Road
Menlo Park, California 94025-3506
Telephone: (650) 324-6951
Facsimile: (650) 324-0638

SV 471304 v1
12/17/03 2:50 PM (22001.0003)